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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/672,683 | 09/26/2003 | Chi-Hung Lin | 9751.106USU1 | 9244 |

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| EXAMINER | |
|---|---|
| HENLEY III, RAYMOND J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/672,683 | LIN ET AL. | |
| | Examiner | Art Unit | |
| | Raymond J Henley III | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Peri d for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16 are* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-16 are* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## CLAIMS 1-16 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment filed September 26, 2003 has been received and entered into the application. Accordingly, the specification has been amended at page 1, line 3.

### *Title*

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### *Claim Rejection - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4 and 6-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting the growth of a human cervical carcinoma cell, a human hepatocellular cell or a breast cancer cell and for treating or alleviating or ameliorating the symptoms associated with cancers caused by such cell types does not reasonably provide enablement for inhibiting the growth of a cancer cell in general or treating or alleviating or ameliorating symptoms of a non-specific cancer type or preventing the symptoms of any type of cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Respecting the aspect of preventing the symptoms of a cancer in general as in present claims 8-16, such is tantamount to the prevention of the cancer itself because one of the

symptoms of cancer is the cancer itself. The burden of enabling the prevention any and all cancers would be much greater than that of enabling the treatment of such conditions. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing of such conditions or how a patient could be kept from ever being susceptible to these conditions. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing the symptoms of any and all cancer types.

Specifically, it is highly unlikely, and the Office would require experimental evidence to support the contention that the claim specified actives could actually prevent any and all cancer types and the symptoms associated therewith by simply administering, by any method, an amount of the claim specified active agents. The specification fails to enable one of ordinary skill in the art to practice and use the compositions/article of manufacture in the present claim for preventing the above conditions.

The term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success. Since absolute success is not reasonably possible with most diseases/disorders, especially those having etiologies and pathophysiological manifestations as complex/poorly understood as cancers in general, the specification, while providing examples of the treatment of 3 specific types of cancers, i.e., cervical, hepatocellular and breast, is viewed as lacking an adequate written description of the where any and all cancers and the symptoms associated therewith may be prevented.

Respecting the aspect of inhibiting the growth of a cancer cell, (present claims 1, 3, 4, 6 and 7) such is considered to be merely a treatment method for cancers developed from such cells.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CaAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

1) Nature of the invention.

The claimed invention is directed to compositions and methods for inhibiting a cancer cell in general in general.

2) State of the prior art.

While the state of the art is relatively high with regard to the treatment of specific cancer types, the state of the art with regard to treating cancer broadly is underdeveloped. In particular, there is no known anticancer agent that is effective against all cancer cell types. The Cecil reference (cited by Examiner) clearly shows that for the various known cancer types, there is not one specific chemotherapeutic agent that is effective for each and every type of cancer (see page Table 198-5 at page 1065; Tables 198-6 and 198-7 at page 1066; Table 198-8 at page 1068; and Table 198-9 at page 1071).

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. However, given the state of the art as set forth above, the artisan is currently unaware of any one particular anticancer agent that is effective against all cancer cell types.

4) Level of predictability in the art.

The lack of significant guidance from the present specification or prior art with regard to the actual treatment of all cancer cells in a mammal, including a human subject, with the claimed active ingredient makes practicing the claimed invention unpredictable.

5) Amount of direction and guidance provided by the inventor.

The guidance given by the specification is merely that the methods and compositions are useful for treating/inhibiting the growth of a cancer cell in general.

6) Existence of working examples.

The specification at page 14, line 1 – page 18, line 6 shows only the treatment of three specific types of cancer cells, i.e., cervical, hepatocellular and breast.

7) Breadth of claims.

The complex nature of the subject matter to which the present claim is directed is exacerbated by the breadth of the claim. The claim is extremely broad due to the vast number of possible cancer types represented by the term "a cancer cell".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. Applicants have failed to provide guidance and information to allow the skilled artisan to ascertain that the present active agent is effective against all types of cancers.

***Examiner's Suggestion for Overcoming this Rejection***

Applicants may wish to consider limiting claims 1 and 4 to the specifically enabled

cancer cell types, i.e, cervical, hepatocellular and breast and limiting claims 8 and 12 to the treatment or alleviating or ameliorating the symptoms of the above cancer types in order to overcome this ground of rejection.

***Claim Rejection - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Bang et al. who teach the administration, which may be oral, of a composition which comprises abietic acid or derivatives thereof and a pharmaceutically acceptable carrier for the following types of cancers: sarcoma, lung, melanoma, ovarian and renal (see the abstract, col. 1, line 55 – col. 3, line 7, col. 3, lines 30-32 and col. 7, lines 12-32 and lines 44-52).

The requirements of claims 3, 6, 10 and 14 regarding the reaction of the tumor or cancer cells and those of claims 8 and 12 respecting the preventing, alleviating or ameliorating the symptoms of a cancer are deemed inherently disclosed in the prior art because the same drugs are being administered to the same host not distinct from those claimed.

To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art

recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

The requirement of claims 7 and 17 that the composition is a dietary supplement and in claim 5 the cell type is human cervical carcinoma or human hepatocellular is deemed met by the prior art teachings because such a requirements represent no more than recitation of intended use and does not impart any physical or otherwise material limitation to the claimed composition that is not found in the prior art compositions.

***Examiner's Suggestion for Overcoming the Rejection***

Applicants may wish to consider limiting claim 1 to the specifically disclosed cancer cell types, i.e, cervical, hepatocellular or breast, and limiting claim 8 to the treatment or alleviating or ameliorating the symptoms of the above cancer types in order to overcome this ground of rejection. Given the unpredictability in the art concerning cancer chemotherapy, the teaching of Bang et al. for treating sarcoma, lung, melanoma, ovarian and renal cancer would not teach or suggest the treatment of any other specific type of cancer, including those of applicants, i.e., cervical, hepatocellular or breast. Similarly, the broad teaching of the reference to treat "tumors" in general would be insufficient to teach or suggest the skilled artisan to treat the specific types of cancers disclosed by applicants, i.e, cervical, hepatocellular or breast.

Cancellation of the claims directed to the compositions of matter is also suggested because the prior art teaches such compositions to be old. Applicants' attention is drawn to In re Dillon, 16 USPQ2nd, 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

***Claim Objection***

Claim 2 is objected to as depending from a rejected base claim, but is otherwise in condition for allowance.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

June 21, 2004